



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/551,898

01/05/2006

Kuniharu Moriwaki

10873.1788USWO

6265

52835

7590

05/28/2008

HAMRE, SCHUMANN, MUELLER & LARSON, P.C.

P.O. BOX 2902

MINNEAPOLIS, MN 55402-0902

EXAMINER

WILSON, LARRY ROSS

ART UNIT

PAPER NUMBER

4166

MAIL DATE

DELIVERY MODE

05/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/551,898	Applicant(s) MORIWAKI ET AL.	
	Examiner LARRY R. WILSON	Art Unit 4166	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 October 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/5/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. Figures 8A and 8B should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over European Patent Application No. EP 664139 to Arakawa, Kuranosuke et al. (Kuranosuke) in view of European Patent Application No. EP 1048311 to Teraoka, Yosisuke (Yosisuke).

In Reference to Claim 1

Kuranosuke teaches:

A medical needle device with winged shield (Fig. 1), comprising:

a winged shield that has a substantially cylindrical shield tube (#2, Fig. 4 and col. 3, lines 38-39) and a pair of wings positioned at a front end side of the shield tube (#4, Fig. 4);

a hub that is inserted into an inner bore of the shield tube (#12, Fig. 4) so as to be movable in an axial direction (col. 3, lines 39-44); and

a needle (#11, Fig. 3) that is mounted to a front end of the hub (#12, Fig. 4 and col. 4, lines 4-6),

a rear end of the hub being capable of being connected with an infusion tube (col. 4, lines 19-20 and col. 6, lines 45-46) and a tip of the needle being capable of being stored in the inner bore of the shield tube (Fig. 4 and col. 3, lines 39-44),

... and is latched to the shield tube (col. 2, lines 21-26).

However, Kuranosuke does not teach:

wherein the shield tube is bendable at least in a part along an axial direction when the needle protrudes from the front end of the shield tube

Yosisuke teaches:

wherein the shield tube is bendable at least in a part along an axial direction when the needle protrudes from the front end of the shield tube (col. 2, lines 22-31) in order to simplify the structure and reduce the manufacturing costs (col. 2, lines 5-6).

It would have been obvious to one skilled in the art at the time of the invention to have included the bendable shield tube at least in a part along an axial direction when the needle protrudes from the front end of the shield tube (col. 2, lines 22-31) in the injector needle assembly of Kuranosuke in order to simplify the structure and reduce the manufacturing costs (col. 2, lines 5-6) as explicitly taught by Yosisuke. It is inherent in the disclosure that an accordion shield capable of stretching and contracting would also be capable of bending, much like a plastic drinking straw stretches, contracts and bends.

In Reference to Claim 2

Kuranosuke teaches:

The medical needle device according to claim 1 (see rejection of claim 1 above), wherein at least a part of the hub is made of a material having flexibility (col. 4, lines 6-10).

In Reference to Claim 3

Kuranosuke teaches:

The medical needle device according to claim 1 (see rejection of claim 1 above), wherein a length of the hub is set so that, when the needle protrudes from the front end of the shield tube (Fig. 3) and is latched to the shield tube (col. 2, lines 21-26), the rear end of the hub is positioned on a side closer to the front end of the shield tube than a rear end of the shield tube (Fig. 3).

In Reference to Claim 4

Kuranosuke teaches:

The medical needle device according to claim 1 (see rejection of claim 1 above),

However, Kuranosuke does not teach:

wherein the shield tube is made of a material having flexibility.

Yosisuke teaches:

wherein the shield tube is made of a material having flexibility (col. 5, lines 24-27 and col. 6, lines 32-36) in order to lower manufacturing costs and simplify the structure (col. 2, lines 5-6).

It would have been obvious to one skilled in the art at the time of the invention to have made the shield tube of a material having flexibility (col. 5, lines 24-27 and col. 6, lines 32-36) in the injector needle assembly of Kuranosuke in order to lower manufacturing costs and simplify the structure (col. 2, lines 5-6) as explicitly taught by Yosisuke. Furthermore, Yosisuke teaches "a material for the protector is not particularly limited and any materials can be used" and it would be within the level of ordinary skill in the art to choose a material for various design reasons including thickness, bacterial impermeability and ease of manufacture/assembly that would have inherently made a shield tube that is flexible.

In Reference to Claim 5

Kuranosuke teaches:

The medical needle device according to claim 1 (see rejection of claim 1 above), and the shield tube and the hub (col. 4, lines 6-10) are bendable at the extendable portion.

However, Kuranosuke does not teach:

wherein the shield tube includes an extendable portion that is structured to be extendable and contractible, the needle can be moved in the axial direction of the shield tube by extending and contracting the extendable portion, and the shield tube and

Yosisuke teaches:

wherein the shield tube includes an extendable portion that is structured to be extendable and contractible (col. 5, lines 24-27), the needle can be moved in the axial direction of the shield tube by extending and contracting the extendable portion (col. 5, lines 27-32), in order to control the "exposed length of the injection needled exposed from the protector can be changed into a desired length" (col. 2, lines 27-29).

It would have been obvious to one skilled in the art at the time of the invention to have incorporated the shield tube with an extendable portion structured to be extendable and contractible (col. 5, lines 24-27), the needle can be moved in the axial direction of the shield tube by extending and contracting the extendable portion (col. 5, lines 27-32) in the injector needle assembly of Kuranosuke in

order to control the "exposed length of the injection needled exposed from the protector can be changed into a desired length" (col. 2, lines 27-29) as explicitly taught by Yosisuke.

In Reference to Claim 6

Kuranosuke teaches:

The medical needle device according to claim 5 (see rejection of claim 5 above),

However, Kuranosuke does not teach:

wherein the extendable portion has a plasticity-processed accordion-like structure.

Yosisuke teaches:

wherein the extendable portion has a plasticity-processed accordion-like structure (col. 5, lines 31-35) in order to optimize "the force required for stretch or contraction" (col. 2, lines 51-52).

It would have been obvious to one skilled in the art at the time of the invention to have modified the shield with an extendable portion that has a plasticity-processed accordion-like structure (col. 5, lines 31-35) of Yosisuke in the injection needle assembly of Kuranosuke in order to optimize "the force required for stretch or contraction" (col. 2, lines 51-52) as explicitly taught by Yosisuke.

In Reference to Claim 7

Kuranosuke teaches:

The medical needle device according to claim 1 (see rejection of claim 1 above), ... the hub in the inner bore of the shield tube are bent (col. 4, lines 6-10) together,

However, Kuranosuke does not teach:

wherein, when the shield tube and ... a minimum radius of curvature at a bent part can be 3 mm or smaller.

Yosisuke teaches:

wherein, when the shield tube (col. 5, lines 24-27) and ... a minimum radius of curvature at a bent part can be 3 mm or smaller.

This is an optimization of parameters, i.e. the particular plastics chosen, as taught by Yosisuke, "a material for the protector is not particularly limited and any materials can be used, for example materials used for a needle base and a wing of a conventional winged injection needle device" (col. 6, lines 40-43). As there is no limitation on the particular materials used to form the shield and hub it would be within the level of those of ordinary skill in the art at the time of the invention to have chosen a material(s) which would provide a particular flow rate, wall thickness (col. 8, lines 33-35), or bacterial impermeability. Through optimizing these parameters with known materials certain flexibility would be inherent. Further, determining the radius of bend would be an optimization problem which would be obvious to one of ordinary skill in the art at the time of the invention (see MPEP 2144.05).

Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 4,177, 809 to Harvey R. Moorehead teaches an intravenous catheter apparatus that has an inserter component that is made of a "flexibly deformable elastomer which is resilient, that is having a memory such that it can be deformed under manual pressure and yet can spontaneously regain its original shape" (col. 3, lines 32-36); the inserter component is relevant because it has a retractable needle. U.S. Patent 4,160,450 to George O. Doherty teaches a retractable needle with a flexible response to manual pressure (col. 3, lines 27-32) and a bellows configuration (Fig. 4).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LARRY R. WILSON whose telephone number is (571)270-5899. The examiner can normally be reached on Monday-Thursday 7:00 AM - 5:30 PM (EST).

6. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kenneth Bomberg can be reached on 571-272-4922. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 4124

7. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LRW

/Kenneth Bomberg/

Supervisory Patent Examiner, Art Unit 4124